

REMARKS/ARGUMENTS

Status of the Claims

Upon entry of the present amendment, Claims 8-41 are pending. Claims 8, 11, 14, 16, 31, 32 and 41 are amended.

In accordance with the Examiner's suggestion, Claims 8 is amended to define the acronym MRE11 and to recite an article before the term "functional effect."

In accordance with the Examiner's suggestion, Claim 11 is amended to insert an article before the term "substrate."

In accordance with the Examiner's suggestion, Claim 14 is amended to recite "MRE11" before the term "polypeptide."

In accordance with the Examiner's suggestion, Claim 16 is amended to insert an article before the term "substrate."

In accordance with the Examiner's suggestion, Claim 31 is amended to recite "a p53 null or mutant cell."

In accordance with the Examiner's suggestion, Claim 32 is amended to recite "a p53 wild-type cell."

In accordance with the Examiner's suggestion, Claims 41 is amended to define the acronym MRE11 and to remove recitation of "SAK" and "a fragment thereof."

Amendments to the Specification

The paragraph at page 2, lines 5-17 is amended to incorporate the definition for the acronym "MRE11." The definition for MRE11 was known in the art and originally defined in Ajimura, *et al.*, *Genetics* (1992) 133:51-66, attached as Exhibit A.

The paragraph at page 3, line 29 through page 4, line 4 is amended to correct a typographical error.

Claim Objections

Claims 8 and 41 were objected to for failing to provide a definition for the acronym "MRE11." In accordance with the Examiner's suggestions, Claims 8 and 41 have been amended to set forth the definition for MRE11.

Claim 11 was objected to for not reciting an article before the word "substrate." In accordance with the Examiner's suggestions, Claim 11 has been amended to recite "a substrate."

Claim 14 was objected to for not reciting the term "MRE11" before the term "polypeptide."

Claim 16 was objected to for not reciting an article before the word "ligand." In accordance with the Examiner's suggestion, Claim 11 has been amended to recite "a ligand."

Claim 31 was objected to for not reciting "a p53 null or mutant cell." This claim has been amended in accordance with the Examiner's suggestion.

Claim 32 was objected to for not reciting "a p53 wild-type cell." This claim has been amended in accordance with the Examiner's suggestion.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claim 8 under 35 U.S.C. § 112, second paragraph, because the recitation of "the functional effect" lacked antecedent basis. In accordance with the Examiner's suggestion, Applicants have amended Claim 8 to recite "a functional effect."

The Examiner rejected Claim 41 for reciting "a SAK polypeptide" and the phrase "fragment thereof." In accordance with the Examiner's suggestion, Applicants have amended Claim 41 to remove recitation of these phrases.

Rejection under 35 U.S.C. § 102(e) over U.S. Patent Publication No. 2002/0115057

The Examiner has rejected Claims 8-10, 12, 14-15, 17, 19, 23-29, 35-36 and 38-40 under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent Publication 2002/0115057 ("Young"). This rejection is respectfully traversed, because Young does not teach or suggest the claimed methods, either expressly or inherently.

The present claims are directed to methods for identifying a compound that modulates cellular proliferation or chemosensitivity. The methods contemplate the specific goal of modulating cellular proliferation or chemosensitivity by contacting the compound with a MRE11 polypeptide. The invention is based in part on the recognition by the present inventors that inhibition of MRE11 is antiproliferative in tumor cells.

Proper anticipation requires that a cited reference teach or suggest each and every element of the invention in the rejected claim, either expressly or inherently. M.P.E.P. § 2131. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherence of that result or characteristic. M.P.E.P. § 2112(IV), *citing In re Rijckaert*, 9. F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original). Where the claimed invention is not expressly disclosed in the cited reference, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *See*, M.P.E.P. § 2112(IV), *citing Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Young does not teach or suggest the claimed methods, either expressly or inherently. Young discloses 2276 nucleotide sequences. In the paragraphs of Young cited by the Examiner (paragraphs 0022, 0029-0039, 0044-0049 and 0069-0070) and throughout the Young publication, Young only generally refers to “the present invention,” “gene or genes,” or “sequences of SEQ ID NO:1-2276.” This includes any one (or more) of the 2276 nucleotide sequences disclosed in Young. In certain instances, for example in paragraph 0045 identified by the Examiner, Young identifies SEQ ID NO:1155 as one of 1020 nucleotide sequences. No particular function is attached to any one (or more) of the 2276 nucleotide sequences of disclosed in Young. The Young disclosure at most guesses by listing possible functions that might possibly be attributed to any one of the 2276 nucleotide sequences. Young does not teach anything regarding the function of any of the 2276 listed nucleotide sequences, including whether they encode a polypeptide. In paragraph 0052, Young conjectures that “[t]he sequences disclosed herein may be genomic in nature . . . or may be a cDNA sequence derived from a messenger RNA (mRNA).” In the one paragraph of Young that mentions cellular proliferation

(paragraph 0092), Young speculates that “[s]ome or all of the genes within the signature gene sets disclosed herein as SEQ ID NO:1-2276 are found to play a direct role in the initiation or progression of cancer or even other diseases and disease processes,” but does not disclose or suggest which nucleotide sequences within the 2276 sequences.

Young refers to “nucleotide sequences,” or “genes,” but does not once attach any particular nucleotide sequence (or polypeptide sequence) SEQ ID NO to a particular function. It is clear from the Young publication that Young does not teach or suggest anything about the particular function or use of any of the 2276 disclosed nucleotide sequences, including the cited SEQ ID NO:1155. Therefore, Young does not teach or suggest any methods of using any of the particular nucleotide sequences. It follows that Young does not teach or suggest, either expressly or inherently, a method of identifying a compound that modulates cellular proliferation or chemosensitivity by contacting a MRE11 polypeptide. Young does not recognize a MRE11 polypeptide, and no method of using a MRE11 polypeptide necessarily flows from the disclosure of Young.

Because Young does not expressly or inherently disclose or suggest the claimed methods, the Examiner is respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 102(e) over U.S. Patent Publication No. 2002/0182586

The Examiner has rejected Claims 8-12, 14-17, 19, 23-30, 34-36 and 38-40 under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent Publication 2002/0182586 (“Morris”). This rejection is respectfully traversed, because Morris does not teach or suggest the claimed methods, either expressly or inherently.

Morris discloses a summary table that lists the names of 343 genes, referring to both human and mouse nucleotide sequences for a total of 686 referenced sequences. However, the sequence listing for Morris is not publicly available through the publication itself, the USPTO internet posting of the publication, or the Publication Site for Issued and Published Sequences (PSIPS). The Examiner cites SEQ ID NO:1223. In the paragraphs of Morris cited by the Examiner (paragraphs 0007-0008, 0010-0011, 0022, 0026-0027, 0076-0077, 0080, 0189, 0191-0195, 0200-0202, 0206 and 0209), Morris only generally refers to “carcinoma-associated

(CA) genes,” “CA sequences,” or “CA proteins.” This includes any one (or more) of the at least 686 nucleotide sequences referenced in Morris’s Table 1. No particular function is attached to any one (or more) of the at least 686 nucleotide sequences of referenced in Morris. The Morris disclosure at most guesses by listing numerous possible functions that might possibly be attributed to any one of the at least 686 referenced nucleotide sequences. Morris does not teach anything regarding the particular function of any of the 686 referenced nucleotide sequences. The CA sequences of Morris were initially identified by infection of mice with murine leukemia virus (MLV) (paragraph 0031). Morris conjectures that the CA sequences may be up-regulated in carcinomas (paragraph 0033); down-regulated in carcinomas (paragraph 0034); altered (paragraph 0035); secreted proteins, transmembrane proteins or intracellular proteins (paragraph 0036). Morris further speculates that CA proteins that are intracellular proteins may have enzymatic activity such as protein kinase activity, protein phosphatase activity, protease activity, nucleotide cyclase activity, or polymerase activity; may serve as docking proteins or targeting proteins to subcellular localizations or involved in maintaining the structural integrity of organelles (paragraph 0037; *see also*, paragraphs 0038-0046).

Morris refers to “CA genes,” “CA sequences,” or “CA proteins,” but does not once attach any particular nucleotide sequence (or polypeptide sequence) SEQ ID NO to a particular function. It is clear from the Morris publication that Morris does not teach or suggest anything about the particular function or use of any of the at least 686 referenced nucleotide sequences, including the cited SEQ ID NO:1223. Therefore, Morris does not teach or suggest any methods of using any of the particular referenced nucleotide sequences. It follows that Morris does not teach or suggest, either expressly or inherently, a method of identifying a compound that modulates cellular proliferation or chemosensitivity by contacting a MRE11 polypeptide. Morris does not recognize a MRE11 polypeptide, and no method of using a MRE11 polypeptide necessarily flows from the disclosure of Morris.

Because Morris does not expressly or inherently disclose or suggest the claimed methods, the Examiner is respectfully requested to withdraw this rejection.

Appl. No. 10/026,331
Amdt. dated July 15, 2005
Reply to Office Action of April 19, 2005

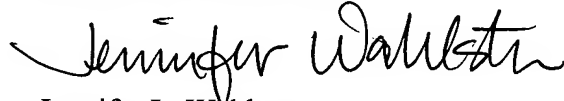
PATENT

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



Jennifer L. Wahlsten
Reg. No. 46,226

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 925-472-5000
Fax: 415-576-0300
Attachments
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